

REMARKS

Claims 1-22 remain pending in this application. Claims 1-5 and 10-22 have been withdrawn from consideration as being directed to a non-elected invention or, in the case of claims 14-22, are allegedly not drawn to statutory subject matter. Applicants affirm the election of the subject matter of claims 6-9 for examination in this application.

Abstract

The Abstract was objected to because it uses legal phraseology. Correction was required. Although applicants respectfully disagree that any correction is required since the guidelines specified in MPEP 601.01(b) express preferences ("should") and not requirements ("must"). Although the abstract as originally filed did describe the disclosure sufficiently - how could anyone seriously contend that terms such as "novel" or "said" could mislead or confuse any reader - the abstract has been amended to avoid the language identified by the Examiner.

Objections:

Claims 6 and 8 have been objected to because of a couple of alleged informalities for which the Examiner has suggested a correction. Accordingly, claim 6 has been amended to recite a "liquid composition," and the term "high-molecular-weight" has been deleted from claim 8. These amendments should avoid the objections.

Rejections: § 112, second paragraph

Claims 6-9 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for several reasons that will be addressed below.

A. Claim 6 is allegedly indefinite because of the recitation of “using a combination of.” This phrase has been deleted and replaced by the term “comprising” to avoid this rejection.

B. Claim 6 also is allegedly indefinite because of the recitation of “cake-like.” It is respectfully submitted that this term would be understood by those skilled in the art, particularly when considering the disclosure of the present application and specifically at page 22, lines 2-15 and Examples. However, in order to advance prosecution, the term “cake-like” has been deleted from claim 6.

C. Claim 6 also is allegedly indefinite because of the parenthetical expression on line 9. This expression has been deleted from the claim.

D. Claim 6 also is allegedly indefinite because the phrase “the powder form freeze-dried composition” in line 15 allegedly lacks antecedent basis. The phrase has been amended so that there is clear antecedent basis in at least line 3 of claim 6.

E. Claim 6 was rejected as indefinite because the term “fine particle fraction” (FPF) is allegedly not defined in the specification to refer to particles having a diameter less than or equal to some maximum value. Applicants respectfully disagree. Reference to page 87, line 15 to page 88, line 20, particularly page 88, line 5 of the specification clearly shows that applicants have defined what is meant by “fine particle fraction” according to the present invention. Specifically, the determination is made using a twin impinger apparatus where the fraction that can be expected to be delivered into the lungs is that in stage 2 (the aerodynamic diameter of particles recovered in this fraction is 6.4 microns or less). The FPF recitation in the claim is defined in the present specification and the claims should be read and interpreted in a manner consistent with

the specification. In addition, the technical literature directed to a determination of FPF using a twin impinger is consistent with the definition in the specification as represented by each of: (1) Meakin et al., "Drug Delivery Characteristics of Bricanyl Turbohaler™ Dry Powder Inhalers," International Journal of Pharmaceutics, 119:91-102 (1995) - see particularly paragraph 2.2.3.1 bridging pages 92 and 93; (2) Steckel et al., "In vitro evaluation of dry powder inhalers I: drug deposition of commonly used devices," International Journal of Pharmaceutics, 154:19-29 (1997) - see particularly page 22 and paragraph 2.4; and (3) Lucas et al., "Protein Deposition from Dry Powder Inhalers: Fine Particle Multiplets as Performance Modifiers," Pharmaceutical Research, Vol. 15, No. 4, pp. 562-569 (1998) - see particularly paragraph under "In Vitro Aerosol Deposition" on page 564. There is nothing in the documents cited by the Examiner that is inconsistent with these teachings regarding FPF when determined using a twin stage impinger as described and defined in the present specification. Accordingly, this rejection should be withdrawn.

F. Claim 8 was rejected because the phrase "high-molecular weight" was regarded as indefinite. This phrase has been canceled from claim 8. Accordingly, this rejection should be withdrawn.

Rejections: § 102

Claims 6-9 have been rejected under both 35 U.S.C. § 102(a) and § 102(e) as being anticipated by Yamashita et al. (US 2003/0101995) (now U.S. Patent No. 7,448,379).

Yamashita et al. does not anticipate the present claims because it does not teach or describe a freeze-dried composition that was prepared by freeze-drying a liquid composition containing ingredients in a non-dissolved form. As noted in col. 15, lines

13-31, of the '379 patent, the freeze-dried composition may be prepared by filling a solution containing a single effective dose of a drug into a vessel and then freeze-drying as is. There is no teaching or description of freeze-drying a composition containing any ingredient in a non-dissolved form. Accordingly, since the '379 patent does not describe each limitation of the present claims, these anticipation rejections should be withdrawn.

As noted in MPEP 2132.01 and MPEP 2136.05, documents that appear to be references under § 102(a) or § 102(e) cannot be used against the inventors named in this application if the subject matter relied on in those documents is a disclosure of the work done by the inventors named in this application. To that end, applicants are filing concurrently with this Reply a Rule 132 declaration of the inventors named in this application stating that the description of the invention that is contained in US 2003/0101995 is a description of their own work that was made independently of the additional inventor, Shigeru Ibargi, named in the published application, but not named in the present application. Accordingly, since neither US 2003/0101995 nor U.S. Patent No. 7,448,379 can be a valid § 102(a) or § 102(e) reference against the present claims, these rejections should be withdrawn.

Double Patenting

Claims 6-9 have been rejected on the ground of obviousness-type double patenting as being unpatentable over claims 1, 75, 83, and 111-114 of allowed copending application 10/170,339 in view of Yamashita et al. (US 2003/0101995). This rejection is a little confusing as the Yamashita et al. publication is the published version of Application No. 10/170,339 - the identical disclosure that has now become U.S. Patent No. 7,448,379. In any event, applicants are avoiding this issue by filing a

terminal disclaimer in this application relative to the '379 patent. Accordingly, this rejection should be withdrawn.

Claims 6-9 also have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8 and 9 of copending Application No. 12/202,220. This rejection is traversed. First, claims 1-6, 8 and 9 of the '220 application have been canceled in a supplemental preliminary amendment filed in that '220 application on December 2, 2008. Second, there is nothing in the pending claims of the '220 application that would teach or suggest using a freeze-dried composition that was prepared by freeze-drying a liquid composition containing ingredients in a non-disclosed form. Accordingly, the claimed invention in this application is not an obvious variant of the invention claimed in the '220 application. Finally, since this issue of prospective double patenting appears to be the last issue remaining in this application, and since a terminal disclaimer has been filed relative to the '379 patent (the parent of the '220 application), this double patenting rejection should be withdrawn and addressed in the '220 application, if appropriate, so this application can be passed to issue. MPEP 804(I)(B), last paragraph.

Prompt and favorable reconsideration is requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Attachments: Meakin et al., International Journal of Pharmaceutics 119 (1995) 91-102
Steckel et al., International Journal of Pharmaceutics 154 (1997) 19-29
Lucas et al., Pharmaceutical Research, Vol. 15, No. 4, 1998
Rule 132 declaration of the inventors
Terminal Disclaimer
Abstract